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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,130	02/05/2002	Olga Bandman	PF-0319-2 DIV	2603

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Legal Department
Incyte Genomics Inc
3160 Porter Drive
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,130	BANDMAN ET AL.	
	Examin r	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12 and 29-45* is/are pending in the application.

4a) Of the above claim(s) *1,12,29,30,33,35,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,31,32,34 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 1, 11, 12, and 29-45 are pending in the instant application.

Applicants' election **with** traverse of Group II, claims 11, 31, 32, 34, and 36-43 in Paper No. 5, filed 12/03/02, is acknowledged.

Election/Restriction

1. Applicants traverse the restriction on the grounds that the claims of Groups V-VII, drawn to methods of using the antibody of Group II, should be rejoined. Applicants argue it would not be an undue burden to search the antibody of Group II and the methods of Groups V-VII. Applicants' argument is not found persuasive. The search of each of Groups II and V-VII would require independent considerations which would require the examiner to focus on different features for the product of Group II or the methods of Groups V-VII and would entail differently structured text searches for both patent and non-patent literature for each of the Groups, thus requiring a serious burden on the examiner. It is noted that If the claims of Group II are found to be allowable, then the claims of Groups V-VII will be evaluated to determine if they are directed to processes of using the patentable product, and if so would be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai*, and *In re Brouwer*). However, as the elected claims of Group II are not yet allowable, rejoinder is not as yet required.

Applicants further traverse on the grounds that co-examination of the claims of elected Group II with the claims of Groups I and III would not result in an undue burden on the examiner as the claims of Groups I and III are related to claims allowed in parent applications. Applicants' argument has been fully considered but is not found persuasive. A search for antibodies that bind to a polypeptide includes not only an extensive search of the polypeptide sequence, but also includes an extensive patent and non-patent literature search for antibodies that bind similar polypeptides to assess their ability to bind the claimed polypeptide and thus act as an antibody to the claimed polypeptide. While the search for

polynucleotides will overlap with portions of the searches for encoded polypeptides and antibodies to said polypeptides, clearly the searches for polypeptides and antibodies are much more extensive resulting in a serious burden on the examiner to search all three patentably distinct inventions. Thus, a serious burden would be required for the examiner to search not only the polynucleotide sequence of Group III and encoded polypeptide of Group I, but also antibodies that bind the encoded polypeptides.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 12, 29, 30, 33, 35, 44, and 45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

Claims 11, 31, 32, 34, 36-43 are being examined on the merits.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: the citizenship of inventor Olga Bandman is not listed.

Specification/Informalities

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Human Protein Phosphatase Antibody". See MPEP § 606.01.

Claim Objections

4. Claims 11, 31, 32, 34, and 36-43 are objected to as being dependent upon a non-elected claim. It is suggested that applicants amend claim 11 to incorporate the limitations of claim 1. For purposes of

examination, claim 11 has been examined as though the limitations of claim 1 have been incorporated into the claim.

5. Claim 39 is objected to in the recitation of "isolating from the culture monoclonal antibody". The term is grammatically incorrect and should be replaced with, for example, "isolating from the culture a monoclonal antibody".

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11, 31, 32, 34, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 (claims 31, 32, 34, and 36-43 dependent thereon) is indefinite in the recitation of "biologically active." The specification discloses the meaning of this term as "having structural, regulatory, or biochemical functions of a naturally occurring molecule" (see page 7 of the instant specification). However, the scope of things encompassed by this "definition" is vague and it is unclear from the definition of this term what functions of SEQ ID NO:1 applicants intend as the meaning of "biologically active". It is suggested that the term "biologically active" be replaced with a term that clearly defines applicants' intended function(s) such as "enzymatically active".

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11, 31, 32, 34, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 (claims 31, 32, 34, 42, and 43 dependent therefrom) is rejected because the claim is drawn to a genus of antibodies that bind: a genus of polypeptides *comprising* SEQ ID NO:1 and a genus of polypeptides *comprising* a genus of naturally-occurring amino acid sequences at least 90% identical to SEQ ID NO:1. The claim is rejected because the genus of polypeptides to which the claimed genus of antibodies binds has not been fully described in the specification. No description has been provided of the genus of polypeptide sequences and compositions encompassed by the claims. No information, beyond the disclosure of the amino acid sequence of SEQ ID NO:1 has been provided by applicants which would indicate that applicants had possession of the claimed genus of antibodies. Regarding parts a) and b) of claim 11, the specification does not contain any disclosure of the structure all polypeptide sequences *comprising* SEQ ID NO:1 or *comprising* a naturally-occurring sequence that is at least 90 % identical to SEQ ID NO:1. The specification discloses only a single species of the claimed genus, i.e., an antibody that specifically binds to the amino acid sequence of SEQ ID NO:1, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Regarding part b) of claim 11, the specification does not contain any disclosure of the function of all the naturally-occurring polypeptide sequences that are at least 90 % identical to SEQ ID NO:1 within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including polypeptides that can have a wide variety of functions and with the potentiality of generating many different antibodies. Therefore many functionally unrelated antibodies are encompassed within the scope of these claims. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 11, 31, 32, 34, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds the amino acid sequence of SEQ

ID NO:1, does not reasonably provide enablement for an antibody that specifically binds: *any* polypeptide *comprising* the polypeptide of SEQ ID NO:1 or *any* polypeptide comprising an amino acid sequence having at least 90 % identity to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make and use the entire scope of claimed antibodies. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claim 11 (claim 31, 32, 34, 42, and 43 dependent thereon) is so broad as to encompass an antibody that specifically binds: *any* polypeptide *comprising* the polypeptide of SEQ ID NO:1 or *any* polypeptide *comprising* an amino acid sequence having at least 90 % identity to SEQ ID NO:1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of antibodies broadly encompassed by the claims. Since the amino acid sequence of a protein determines the antibody elicited thereby, predictability of which changes can be made in a protein's amino acid sequence and retain the desired antibody binding affinity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence comprise the antibody binding region or epitope. In the instant case, the disclosure is limited to an antibody that specifically binds the polypeptide of SEQ ID NO:1. Applicants have provided guidance only for generating antibodies that specifically bind the amino acid sequence of SEQ ID NO:1. There is no disclosure in the specification or the prior art as to other polypeptides that comprise the polypeptide of SEQ ID NO:1 or other polypeptides comprising an amino acid sequence that have 90 % or more identity to SEQ ID NO:1. There is no guidance in the specification or the prior art as to making and using the entire scope of antibodies that

bind *any* polypeptide *comprising* the polypeptide of SEQ ID NO:1 or *any* polypeptide *comprising* an amino acid sequence having at least 90 % identity to SEQ ID NO:1. It is not routine in the art to screen for multiple substitutions or modifications of an antibody binding target, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in retaining the desired antibody binding are limited in any protein and the result of such modifications is unpredictable. It is known in the art that naturally-occurring proteins sharing sequence identity of at least 90% can have altered functions (see for example, Seffernick et al. *J Bacteriol* 183:2405-2410). While Seffernick et al. characterize their finding as highly exceptional, their evidence nonetheless provides support for the unpredictability of variants having identical function.

The specification does not support the broad scope of the claims which encompass an antibody that specifically binds: any polypeptide *comprising* the polypeptide of SEQ ID NO:1, *any* polypeptide having at least 90 % identity to SEQ ID NO:1 because the specification fails to teach how to make and use an antibody that binds any polypeptide *comprising* SEQ ID NO:1 as the claim, as written, does not require the antibody to specifically bind SEQ ID NO:1, but allows for an antibody that is specific for amino acid sequence other than SEQ ID NO:1 that *comprises* the polypeptide. Furthermore, the specificity of an antibody is dependent on the structure of the polypeptide from which it was produced. Therefore, an antibody that binds an epitope within a specific sequence, e.g., the polypeptide of SEQ ID NO:1, will not necessarily bind a polypeptide that shares at least 90 % identity to SEQ ID NO:1 because the epitope may not be present in a polypeptide with at least 90 % identity to SEQ ID NO:1.

Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including an antibody that specifically binds: *any* polypeptide *comprising* the polypeptide of SEQ ID NO:1 or *any* polypeptide *comprising* an amino acid sequence having at least 90 % identity to SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

9. All claims are rejected. No claim is in condition for allowance.

10. Claims 11, 31, 32, 34, and 36-43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1600~~ 1650